

BC Cancer Agency
CARE + RESEARCH
An agency of the Provincial Health Services Authority

International perspectives on Radiation Protection – Canadian Experience

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Outline

- Background
- Canadian Nuclear Safety Commission
- Health Canada
- Provincial Variations
- Conclusions

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Map of Canada



Population estimate (April 2011) : 34,349,236

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Canadian Nuclear Safety Commission (CNSC)

The CNSC regulates the use of nuclear energy and materials to protect the health, safety and security of Canadians and the environment; and to implement Canada's international commitments on the peaceful use of nuclear energy.

CNSC was established in 2000 under the Nuclear Safety and Control Act and reports to Parliament through the Minister of Natural Resources. CNSC was created to replace the former Atomic Energy Control Board (AECB), which was founded in 1946.

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Canadian Nuclear Safety Commission (CNSC)

Class II Nuclear Facilities and Prescribed Equipment

- a particle accelerator that is capable of producing nuclear energy
- a radioactive source teletherapy machine
- a brachytherapy remote afterloader
- Nuclear Medicine facilities

These facilities are highly regulated and thoroughly inspected

Radiation Protection in Diagnostic Imaging

In Canada, the responsibility for radiation protection in diagnostic imaging is shared among the federal government, the provincial/territorial governments and various professionals involved in equipment/facility safety and the delivery of care to patients.

Health Canada

Health Canada partners closely with other federal departments, provincial/territorial governments and health organizations to ensure its efforts meet the radiation protection needs of Canadians.

Health Canada's Activities

- Administration of legislation to ensure safety and effectiveness of radiation-emitting medical devices imported and sold, advertised and manufactured in Canada.
- Assessment of risks from radiation emitting devices
- Research/surveillance to support evaluation of the safety and risks associated with radiation emitting devices
- Providing guidance and information to Canadians to reduce risks from radiation-emitting devices.

Health Canada - Legislation

All radiation-emitting medical devices must meet the requirements of :

- *Food and Drugs Act and Medical Devices Regulations*
- *Radiation Emitting Devices (RED) Act and Regulations*

Food and Drugs Act and Medical Devices Regulations



- The Food and Drugs Act and Medical Devices Regulations are the tools used to ensure that safe and effective devices are available in Canada.
- Manufacturers of devices required to apply to Health Canada to receive either a Licence or an Authorization to sell their devices.

Health Canada Medical Devices Regulations

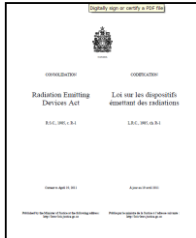


Food and Drugs Act and Medical Devices Regulations

Other Provisions include:

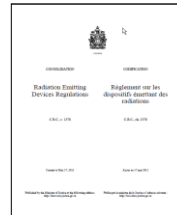
- Mandatory Problem Report
- Recalls
- Complaint Handling / Distribution Records
- Special Access - devices for emergency use or if conventional therapies have failed, are unavailable or are unsuitable
- Investigation Testing – clinical trials involving human subjects.

Radiation Emitting Device Act and Regulations



- Applies to all devices that emit radiation in the form of **electromagnetic energy** (e.g. x-rays, microwaves, radiofrequency (RF) waves, infrared (IR), visible light and ultraviolet (UV) light) or **acoustical energy** (e.g. sound and ultrasound).

Radiation Emitting Device Regulations



Regulations set out standards for labelling/information, construction and performance of radiation emitting devices.

Part II, Dental X-ray Equipment

Part XII, Diagnostic X-ray Equipment

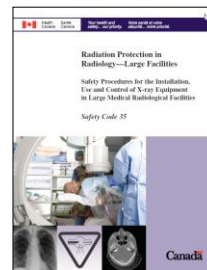
- Radiography Equipment
- Radioscopy Equipment
- Mammography Equipment

Guidance Documents/Information to Canadians

Health Canada provides guidance and information on radiation protection:

- Develops and updates guidelines and safety codes
- Provides advice and expertise to other government departments, agencies, industry.
- Responds to enquiries from the public on radiation safety issues.

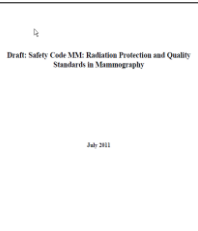
Guidance Documents/Information to Canadians



Health Canada Safety Codes

- Series of documents to set out requirements for the safe use of radiation-emitting devices.
- Written primarily for the instruction and guidance of persons employed in federal public service departments and agencies, as well as those under the jurisdiction of the Canada Labour Code.
- Included mandatory and recommended practices for ensuring radiation safety in medical radiological facilities
- Widely used in provincial/territorial radiological facilities (hospitals and clinics) as well as teaching institutions and referred to in some provincial legislation.

Guidance Documents/Information to Canadians



Current National Consultation:
New Safety Code on Mammography

You are invited to participate:
Consultation - Safety Code Mammography
Consumer and Clinical Radiation
Protection Bureau
Health Canada
775 Brookfield Road, PL 6301A
Ottawa, ON K1A 1C1

Tel: 613 954-6699
Fax: 613 941-1734
CCRPB-PCRPPC@HC-SC.GC.CA,

Consultation ends October 31, 2011

Radiation Protection in Diagnostic Imaging

Provincial Level



Radiation Protection in Diagnostic Imaging

Nova Scotia & New Brunswick

- Shifted from Provincial Dept. of Health to Dept. of Labour
- Focuses more on worker safety than patient safety
- No functioning radiation protection entity which is responsible for patient protection

Radiation Protection in Diagnostic Imaging

Prince Edward Island

- Provincial Dept. of Health through the Chief Health Officer / Environment Health Office
- Provincial Regs refer to Health Canada safety Codes
- No Qualified Inspectors to inspect medical, dental, chiropractor, veterinarian and industrial facilities
- Health Canada provided inspectors until last year

Radiation Protection in Diagnostic Imaging

Quebec

- "Laboratoire de Santé publique du Québec (LSPQ)" is in charge of issuing licences to radiology clinics (private)
- It also operates a provincial license program to mammography clinics (more stringent than CAR accreditation)
- Hospitals don't need a license from LSPQ, but have to abide to more general instructions from the ministry
- Hospitals are not subjected to direct verification by LSPQ as clinics are

Radiation Protection in Diagnostic Imaging

Ontario

- The Healing Arts Radiation Protection (HARP) Act, Revised Statutes of Ontario, 1990, and the X-ray Safety Code (Regulation 543) cover the use of x-rays for the irradiation of human beings in the province of Ontario.
- HARP Act also authorizes inspectors from MOHLTC to examine x-ray machines, their operation, and the premises where such machines are installed
- No references to Medical Physicists

Radiation Protection in Diagnostic Imaging

Manitoba

- Radiation Protection Department is part of Medical Physics at CancerCare Manitoba
- Responsible for inspection of DI facilities and enforcing relevant provincial regulations.
- The department has a number of inspectors who visit all sites regularly
- Imaging physics department provide acceptance/annual testing and other QC services, although no regulatory mandate

Radiation Protection in Diagnostic Imaging

Saskatchewan

- The Radiation Health and Safety Act, 1985 and The Radiation Health and Safety Regulations, 2005 govern the province's radiation standards for the safety of radiation device users and the public and outlines the responsibilities of the Radiation Safety Unit
- Radiation Safety Unit works to ensure that owners and operators of radiation devices and the public are not exposed unnecessarily to radiation
- Operated under the Ministry of Advanced Education, Employment and Immigration

Radiation Protection in Diagnostic Imaging Alberta

- Radiation Protection act and regs. - All radiation equipment be provincially registered which includes acceptance testing and retesting every four years.
- Acceptance testing requirements generally follow Health Canada Safety Codes
- Government Organization Act, Radiation Health Administration Organization regs. - creates Authorized Radiation Health Administration Organizations (ARHAOs) to issue registration certificates and Authorized Radiation Protection Agencies (ARPAs) to inspect radiation equipment

Radiation Protection in Diagnostic Imaging Alberta – contd.

- Health Professions Act and Regs: gives College of Physician and Surgeons of Alberta (CPSA) authority to set Diagnostic Imaging Standards, establish Diagnostic Imaging Accreditation programs

Radiation Protection in Diagnostic Imaging British Columbia

- Ministry of Health had a Radiation Protection Services division – provided radiation protection services including inspections.
- It is now part of the BCCDC and does not provide those services.
- Occupational Health and Safety Regulation refers directly to Health Canada Safety Codes (*including future publications*)
- WorkSafeBC is mandated to monitor compliance with OHSR

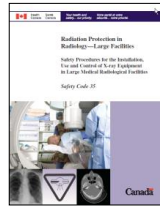
Radiation Protection in Diagnostic Imaging British Columbia – contd.

- Since 1971, the Diagnostic Accreditation Program (DAP) has been mandated to assess the quality of diagnostic services in the province of British Columbia through accreditation activities.
- As a Program of the College of Physicians and Surgeons of British Columbia, the mandate of the DAP derives from the Health Professions Act: Bylaws of the College of Physicians and Surgeons Part 5 Section B.

Radiation Protection in Diagnostic Imaging British Columbia – contd.



www.dap.org



2008

Radiation Protection in Diagnostic Imaging HC Safety Code 35

1.4 Medical Physicist/Radiation Safety Officer

There must be a **Medical Physicist** or Radiation Safety Officer to act as an advisor on all radiation protection aspects during the initial stages of construction of the facility, installation of the equipment, and during subsequent operations. **Medical physicists** are health care professionals with specialized training in the medical applications of physics. A radiation safety officer is the title commonly assigned to a radiation safety specialist who routinely manages a facility's radiation protection program.

The **medical physicist** /radiation safety officer must:

1. possess qualifications required by any applicable federal, provincial, or territorial regulations or statutes and be certified according to a recognized standard, such as
 - for **medical physicists**, the Canadian College of Physicists in Medicine;
2. acquire re-qualification or refresher training according to any applicable federal, provincial, or territorial regulations or statutes and according to a recognized standard, such as
 - for **medical physicists**, the Canadian College of Physicists in Medicine;

Conclusions

Radiation protection regulations and requirements in Canada vary according to the existence/non existence of provincial requirements.

Health Canada Safety Codes provide a common ground for Canada wide, consistent, radiation protection for workers and patients in Diagnostic Imaging.

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